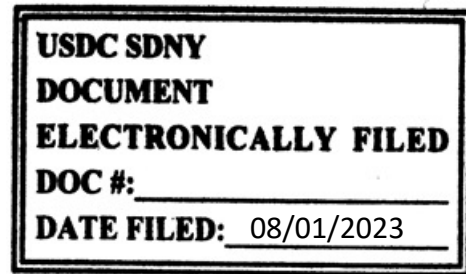


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

ALL ACTIONS



Master File No. 1:13-cv-09244 (RA) (SDA)

OPINION AND ORDER

STEWART D. AARON, United States Magistrate Judge:

Presently before the Court is a dispute regarding a privileged document referred to by the parties as the “Inaba Memo,” which is a January 30, 2009 document authored by Atsuhiro Inaba (“Inaba”),¹ the first page of which contains the production page number TAKACTOS_000527151. (See Pls.’ 7/25/23 Ltr. Mot., ECF No. 531/532, at 2 & Ex. A (ECF No. 531-2).) For the reasons set forth below, the Court finds that Takeda has waived privilege with respect to the Inaba Memo.

BACKGROUND

This is an antitrust class action in which Plaintiffs allege that Takeda prevented competitors from timely marketing a generic version of Takeda’s diabetes drug ACTOS by falsely describing two patents to the Food and Drug Administration (“FDA”). See *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 92 (2d Cir. 2017). As part of its regulatory compliance defense, Takeda chose to expressly waive privilege with respect to the applicability of pre-2003 regulations governing the submission of patent information to the FDA for the two subject

¹ Inaba, an employee of Takeda’s Japanese parent company, Takeda Pharmaceutical Company Limited (Defs.’ 4/7/22 Ltr., ECF No. 487, at 4), was identified in contemporaneous email communications as “Chief Patent Counsel” for Takeda Pharmaceuticals North America, Inc. (See, e.g., 10/18/20 Takeda email, ECF No. 483-6.)

patents, and Takeda's compliance with the pre-2003 regulations. *See In re Actos Antitrust Litig.*, 628 F. Supp. 3d 524, 534-35 (S.D.N.Y. 2022).

Following Takeda's waiver of privilege, the Inaba Memo was produced by Takeda in 2022. (See Pls.' 9/8/22 Ltr. Reply, ECF No. 405, at 13-14; Defs.' 7/28/23 Ltr. Resp., ECF No. 536, at 1.)² The Inaba Memo later was filed by Plaintiffs under seal on September 8, 2022 as an exhibit to a Letter Reply filed by Plaintiffs regarding documents subject to Takeda's privilege waiver. (Pls.' 9/8/22 Ltr. Reply, Ex. F, ECF No. 405-6.) On September 9, 2022, during a telephone conference with the Court addressing the scope of Takeda's waiver, Takeda's counsel stated on the record that Takeda was not seeking to claw back the Inaba Memo. (See 9/9/22 Tr., ECF No. 410, at 6 ("No, we are not proposing to claw back any of the documents that are attached to the reply brief.")) In addition, Takeda's counsel stated, with respect to the documents that were exhibits to Plaintiffs' Letter Reply (which included the Inaba Memo), that Takeda had "endeavored to produce documents that related to the subject matter of the waiver." (*Id.*; see also *id.* at 5 ("we did intend to produce those documents")) Thereafter, on September 16, 2022, this Court issued its Opinion and Order regarding the scope of Takeda's waiver of privilege. *See In re Actos Antitrust Litig.*, 628 F. Supp. 3d at 534-36.

On November 4, 2022, during a meet and confer regarding the scope of Takeda's privilege waiver, counsel for Plaintiffs and counsel for Takeda specifically discussed the Inaba Memo. (See Weiner Decl., ECF No. 532-1, ¶ 2.) During the meet and confer, Plaintiffs' counsel reminded

² On the present record, it is unclear whether Takeda first produced the Inaba Memo in August 2022, as Takeda posits (see Defs.' 7/28/23 Ltr. Resp. at 1), or in May 2022, as Plaintiffs state. (See Pls.' 7/25/23 Ltr. Mot. at 1; Fernández-Silber Ltr., ECF No. 531-6, at PDF p. 6; see also Pls.' 7/31/23 Reply, ECF No. 537 at 3 n.4 ("Plaintiffs' document management system shows the Inaba Memo was produced in a May 2022 production. Takeda asserts that it was first produced unredacted on August 8, 2022."))

Takeda's counsel that the Inaba Memo had been attached to a filing made by Plaintiffs on September 8, 2022, and that Takeda's counsel represented at the hearing on September 9, 2022 that the document would not be clawed back. (*See id.*) Takeda's counsel never stated during the meet and confer that the Inaba Memo was inadvertently produced and would be clawed back. (*See id.*)

On February 27, 2023, Plaintiffs sent Takeda a letter regarding Takeda's assertions of privilege. (Pls.' 2/27/23 Ltr., ECF No. 532-5.) In that letter, Plaintiffs identified the Inaba Memo and requested that the cover email be produced without any redactions. (*See* Pls.' 7/25/23 Ltr. Mot at 2; *see also* Pls.' 2/27/23 Ltr. at PDF p. 5 (identifying TAK-ACTOS_000527151).) Following another meet and confer between counsel, Takeda agreed to re-review the documents subject to the letter. (Pls.' 7/25/23 Ltr. Mot at 2.) As a result of its review, Takeda did not claw back the Inaba Memo but, on March 17, 2023, Takeda reproduced the Inaba Memo, removing the earlier redactions to the cover email. (*Id.*)

Later, on April 3, 2023, Plaintiffs again filed the Inaba Memo under seal, this time in connection with Plaintiffs' Letter Motion to compel Takeda to produce documents subject to the Court's September 16, 2022 Order. (*See* Fernández-Silber Decl., Ex. A, ECF No. 480-1, at PDF pp. 13-15.) On April 7, 2023, Takeda's counsel sought to claw back the Inaba Memo, pursuant to Section 11 of the Protective Order,³ on the ground that it had been inadvertently produced. (*See*

³ Section 11(a) of the Protective Order provides in relevant part:

The inadvertent production of any document, by any party or person, that such party or person later claims should have been withheld on grounds of a privilege (an "Inadvertently Produced Privileged Document"), including but not limited to the attorney-client privilege, the work product doctrine, a joint defense or common interest privilege, or other applicable privilege will not be deemed, in itself, to waive any privilege

DiMattio 4/7/23 Email, ECF No. 531-6, at PDF p. 5.) On April 11, 2023, at 1:31 p.m., Plaintiffs' counsel sent by email a detailed letter explaining why they opposed the claw back and arguing that "the circumstances surrounding Takeda's production of the Inaba Memo clearly indicate intentional disclosure." (See Fernández-Silber Ltr., ECF No. 531-6, at PDF pp. 4-8.) On April 11, 2023, at 5:31 p.m., Takeda's counsel responded by stating: "We are investigating the statements in your letter regarding TAK ACTOS_000527151." (See Huyett 4/11/23 email, ECF No. 531-6, at PDF pp. 3-4.) Then, on the evening of April 12, 2023, Takeda's counsel sent an email stating that, although they were "maintain[ing] [their] position that unredacted portions of TAK-ACTOS_000527151 were inadvertently produced," they were agreeing to withdraw their claw back "in light of the statements made during the September 9, 2022 hearing and the passage of time." (See 4/12/23 Fee email, ECF No. 531-6, at PDF p. 3.)

Takeda asserts that, in the course of preparing Inaba for his deposition in July 2023, Takeda's counsel learned for the first time that the legal analysis and advice provided in the Inaba Memo was not generated by Inaba himself, but that he was recounting advice provided during a meeting that took place in Chicago in January 2009 that was attended by Takeda in-house counsel and outside patent litigation counsel. (Defs.' 7/28/23 Ltr. Resp. at 2.) According to Takeda, "any lingering questions as to whether the Inaba Memo was privileged and not within the scope of Takeda's waiver. . . were put to rest by this new information." (*Id.*) When Plaintiffs' counsel

or work product protection either as to specific information in the Inadvertently Produced Privileged Document or as to any other information relating thereto or on the same or related subject matters.

(Protective Order, ECF No. 190, at 13.)

marked the Inaba Memo as an exhibit at Inaba's deposition on July 21, 2023, Takeda sought to claw it back. (See Inaba Dep., ECF No. 536-2, at PDF pp. 5-6.)

LEGAL STANDARDS

The party who invokes the privilege "bears the burden of establishing its essential elements." *United States v. Mejia*, 655 F.3d 126, 132 (2d Cir. 2011). "The party invoking the privilege also has the burden to show that the privilege has not been waived." *Wultz v. Bank of China Ltd.*, 304 F.R.D. 384, 391 (S.D.N.Y. 2015).

Rule 502(b) of the Federal Rules of Evidence provides:

(b) Inadvertent Disclosure. When made in a federal proceeding or to a federal office or agency, the disclosure [of material protected by attorney-client privilege or the work product doctrine] does not operate as a waiver in a federal or state proceeding if:

- (1) the disclosure is inadvertent;
- (2) the holder of the privilege or protection took reasonable steps to prevent disclosure; and
- (3) the holder promptly took reasonable steps to rectify the error, including (if applicable) following Federal Rule of Civil Procedure 26(b)(5)(B).

Fed. R. Evid. 502(b).

"[C]ourts have held that where parties execute [a protective] order, waiver is appropriate only if production of the privileged material was completely reckless." *Sure Fit Home Prods., LLC v. Maytex Mills Inc.*, No. 21-CV-02169 (LGS) (GWG), 2022 WL 1597000, at *1 (S.D.N.Y. May 20, 2022) (citations & internal quotation marks omitted). "For a production to be completely reckless, the producing party must have shown no regard for preserving the confidentiality of the privileged documents." *Id.* (citations & internal quotation marks omitted).

APPLICATION

Regardless of which waiver standard is applied,⁴ the Court finds that Takeda has failed to meet its burden to show that the privilege has not been waived with respect to the Inaba Memo. Even under the “completely reckless” waiver standard, the record shows that Takeda has waived privilege with respect to the Inaba Memo.

It may be that the initial production of the Inaba Memo was not completely reckless. However, Takeda’s conduct after its production of the Inaba Memo has been completely reckless, as Takeda has “shown no regard for preserving the confidentiality of” the Inaba Memo following its production. *See Sure Fit Home Prods., LLC*, 2022 WL 1597000, at *1.

Takeda had multiple opportunities prior to July 21, 2023 to exercise its rights under the Protective Order and/or Privilege Log Order, and insist upon clawing back the Inaba Memo. Takeda could have done so during the September 9, 2022 hearing, during the November 4, 2022 meet and confer, when it reproduced the Inaba Memo in March 2023 and when it made and then withdrew its claw back request in April 2023.⁵ At bottom, the Court agrees with Takeda’s assessment after Takeda first sought to claw back the Inaba Memo in April 2023, and Plaintiffs resisted. That is, “in light of the statements made [by Takeda] during the September 9, 2022

⁴ Plaintiffs point to the Privilege Log Order, which sets forth the claw back procedure, and provides that “Federal Rule of Evidence 502 shall apply in all respects” (Priv. Log Order, ECF No. 377, at 4), and argue that “[t]he Protective Order . . . does not supplant Federal Rule of Evidence 502(b) and governing case law requiring a party to promptly take reasonable steps to rectify a purported inadvertent disclosure.” (Pls.’ 7/31/23 Reply at 1.)

⁵ The Court acknowledges Takeda’s argument that “any lingering questions as to whether the Inaba Memo was privileged and not within the scope of Takeda’s waiver . . . were put to rest by . . . new information” learned in July 2023 when preparing Inaba for his deposition. (*See* Defs.’ 7/28/23 Ltr. Resp. at 2.) However, Takeda’s counsel had the opportunity over the course of many months to learn this information, and in particular when it “investigat[ed] the statements” regarding the Inaba Memo in April 2023 (*see* Huyett 4/11/23 email, ECF No. 531-6, at PDF pp. 3-4), yet chose not to claw it back at that time.

hearing^[6] and the passage of time,” clawing back the Inaba Memo is not appropriate. (See 4/12/23 Fee email at PDF p. 3.)

CONCLUSION

By reason of the foregoing, the Court finds that Takeda has waived privilege with respect to the Inaba Memo. It is Ordered that Plaintiffs’ Letter Motion filed at ECF No. 531 shall be maintained under seal. The Court finds that the proposed redactions and sealing requests are narrowly tailored to prevent unauthorized dissemination of sensitive business information. See *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119-20 (2d Cir. 2006).

The Clerk of Court is respectfully directed to terminate the gavels at ECF Nos. 531 and 532.

SO ORDERED.

Dated: New York, New York
August 1, 2023



STEWART D. AARON
United States Magistrate Judge

⁶ See *Syntel Sterling Best Shores Mauritius Ltd. v. TriZetto Grp.*, 328 F.R.D. 100, 118 (S.D.N.Y. 2018) (“In order for the Court to conduct proceedings properly, it must be able to rely upon representations made on the record by attorneys licensed to practice before it.”).